NEO PS Knee System
510(k) Summary

MAY 0 3 2013

Device Proprietary Name:	NEO PS Knee System
Common Name:	Total Knee System
Classification regulation:	888.3560
Device Class:	Class II
Product Codes:	JWH (cemented knees)

Submitter's Name:	Pipeline Orthopedics
Address:	3 Wing Drive, Suite 200, Cedar Knolls, NJ 07927
Contact Person:	Robert C. Cohen
Telephone Number:	(973) 267-8800
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Date Summary Prepared:	August 6, 2012

Device Description:
The NEO PS Knee System includes components designed for total knee replacement. The system includes femoral components, tibial inserts, tibial trays, patellar components and surgical instrumentation.

The Neo PS Knee System femoral component, when used with the Neo PS articular surfaces, is designed to achieve flexion at high angles and provide a clinical ROM up to 150 degrees.

Intended Use
The NEO™ PS Knee System components are indicated for use in skeletally mature individuals, with severe knee pain and disability, with excised posterior cruciate ligament, undergoing surgery for total knee replacement due to:

- Osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, moderate deformities and femoral condyle osteonecrosis.
- Failed osteotomies, partial knee replacement, or failed prior total knee replacement whose age, weight and activity level are compatible with an adequate long-term result.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate valgus, varus, or flexion deformities.

NEO™ PS Total Knee System components are indicated for use only with cement and are single use devices.

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Predicate Devices:
The NEO CR Knee System is similar to several predicates including the following.

Trade/Proprietary Name	Manufacturer	510(K) #	Clearance Date
NEO CR Knee System	Pipeline	K120313	4/20/2012
NexGen® LPS-Flex Knee System	Zimmer	K072619 K042271 K991581	11/21/2007 10/13/2004 07/30/1999
Triathlon PS Knee System	Stryker	K031729	9/2/2003

Technological Characteristics:
The metals and standard UHMWPE material from which the components are manufactured are the same materials used in the predicate knee systems and comply with applicable implantable materials standards. A comparison of design features of the NEO PS Knee System to the predicate knee systems and performance testing confirm that the NEO PS Knee System is capable of withstanding the anticipated physiological conditions associated with the indications for use and is substantially equivalent to the predicate devices.

Performance Testing:
The NEO PS Knee System has been evaluated for tibial tray fatigue strength, insert locking mechanism strength, femorotibial range of motion, PS post strength, femorotibial range of constraint, patellofemoral range of constraint, femorotibial contact areas/contact stress, and patellofemoral contact area and contact stress.

Substantial Equivalence Information:
The NEO PS Knee System is similar to legally marketed devices listed previously in that they share similar indications for use and incorporate similar technological characteristics. All evaluations determined that the NEO PS Knee System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 3, 2013

Pipeline Orthopedics
% M Squared Associates, Incorporated
Ms. Terry Sheridan Powell
901 King Street, Suite 102
Alexandria, Virginia 22314

Re: K122500
Trade/Device Name: NEO PS Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: April 24, 2013
Received: April 25, 2013

Dear Ms. Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: To be assigned

Device Name: NEO PS Knee System

Indications for Use:

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices